DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 9, 2010, has been entered.

Acknowledgments

2. In the reply, filed on March 9, 2010, Applicant cancelled claims 7, 8, 13, and 14.

3. Applicant amended claims 1, 9, 15, 16, 18, and 21-23.

4. Currently, claims 1-6, 9-12, and 15-25 are under examination.

Claim Objections

5. Claim 1 is objected to because of the following informalities:

In regards to claim 1, "a inflatable balloon" should be corrected as "an inflatable balloon".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 12, the claim recites that the distal end of the catheter is in sliding engagement with the stiffening member. Claim 12 depends upon claim 9 which depends upon claim 1. Claim 1 recites that the stiffening member is fixedly and non-removably connected to the catheter. Hence, it is unclear how the distal end of the catheter can be in sliding engagement with the stiffening member if the stiffening member is fixedly and non-removably connected to the catheter.

In regards to claim 19, the claim introduces "an inflation device". Claim 19 depends upon claim 1. Claim 1 already introduces "an inflation device". Therefore, it is unclear whether the two inflation devices recited in claims 1 and 19 are the same component or two different components.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6, 9, 15, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell (US 6,135,982).

In regards to claim 1, Campbell teaches a balloon catheter (Figures 1-6, balloon catheter [2]) comprising:

a. an inflatable balloon (balloon [20]) comprising a balloon wall defining an interior volume, the balloon further comprising a distal end (distal end portion [26]), a proximal end (proximal end portion [24]), and a central portion disposed therebetween, the distal end comprising a tubular sleeve (tip [22]) defining a passageway extending partially there through, the passageway terminating in a closed distal terminus

b. a catheter (catheter body [12] with flexible body portion [14]) comprising a distal end portion and a proximal end portion, the proximal end portion comprising a connector (coupling [16]) configured to engage an inflation device (inflation/deflation controller [32]), the distal end portion fixedly connected to the proximal end of the balloon [20], and a lumen extending through the catheter along an axis thereof and in fluid communication with the interior volume of the balloon

c. a stiffening member (core wire [46] with spanning region [18]) comprising a distal portion extending distally from the distal end portion of the catheter [14] and through the interior volume of the balloon [20], the stiffening member comprising a proximal portion extending through the lumen of the catheter and being fixedly and non-removably connected to the catheter at one or more locations, the distal portion of the stiffening member being non-fixedly connected to the distal end of the balloon (column 4, lines 1-10)

d. wherein movement of the distal end [26] of the balloon [20] relative to the proximal end [24] of the balloon is not restrained by the catheter [14] (Figures 2-4)

e. wherein axial movement of the distal end [26] of the balloon [20] relative to the proximal end [24] of the balloon in a direction generally parallel to the axis of the catheter is not restrained by the stiffening member [18] (Figures 2-4)

f. wherein the distal portion of the stiffening member [18] comprises a distal end that is disposed within the passageway of the sleeve [22] and is in slidable engagement with an interior surface of the sleeve, the distal end being spaced proximally from the distal terminus of the passageway so as to permit axial movement of the distal end of the balloon [20] relative to the stiffening member (Figures 2-6)

g. wherein transverse movement of the distal end [26] of the balloon [20] relative to the proximal end [24] of the balloon in a direction generally perpendicular to the axis of the catheter is continuously restrained by lateral engagement between the sleeve [22] and the distal portion of the stiffening member [18] (Figures 2-6)

In regards to claim 2, Campbell teaches that the balloon [20] has a deflated axial length when deflated (Figure 4), and an inflated axial length when inflated (Figure 2), the deflated axial length and the inflated axial length each being defined by the distance between the proximal end [24] and the distal end [26] of the balloon, the deflated axial length being different than the inflated axial length (Figures 2 and 4).

In regards to claim 3, Campbell teaches that the balloon [20] has a deflated axial length when deflated (Figure 4), and a partially inflated axial length when partially inflated (Figure 3), the deflated axial length and the partially inflated axial length each being defined by the distance

between the proximal end [24] and the distal end [26] of the balloon, the deflated axial length being different than the partially inflated axial length (Figures 3-4).

In regards to claim 4, Campbell teaches that the balloon [20] has a partially inflated axial length when partially inflated (Figure 3), and a fully inflated axial length when fully inflated (Figure 2), the partially inflated axial length and the fully inflated axial length each being defined by the distance between the proximal end [24] and the distal end [26] of the balloon, the partially inflated axial length being different than the fully inflated axial length (Figures 2-3).

In regards to claim 5, Campbell teaches that the balloon wall comprises a non-elastic material (column 2, lines 33-34).

In regards to claim 6, Campbell teaches that the balloon wall comprises axially oriented creases or pleats (lobes [42]) to facilitate radial compression of the balloon [20] when deflated (Figure 4A).

In regards to claim 9, Campbell teaches that the lumen of the catheter [14] has a first cross-sectional area and the proximal portion of the stiffening member [18] has a second cross-sectional area, the second cross-sectional area being less than the first cross-sectional area so as to permit an inflation fluid to flow through the lumen between the connector [16] on the proximal end portion of the catheter and the interior volume of the balloon [20] (Figures 1-4).

In regards to claim 15, Campbell teaches that the sleeve [22] comprises a cannula (hypotube [54]) disposed therein, the cannula having an interior surface defining a cross-sectional area that is less than an interior cross-sectional area of the sleeve, the interior surface of the cannula being configured to slidingly engage an exterior surface of the stiffening member [18] (Figures 5-5A).

In regards to claim 18, Campbell teaches that the distal end [26] of the balloon [20] comprises an end cap [22] affixed thereto, the sleeve being defined by the interior volume of the end cap (Figures 1-4).

In regards to claim 19, Campbell teaches an inflation device [32] for inflating or deflating said balloon [20], said inflation device being attached to the connector [16] on the proximal end portion of the catheter [14] (Figure 1).

In regards to claim 21, Campbell teaches that the stiffening member [46] comprises a solid wire having a circular cross-section (column 4, lines 25-27).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, as applied to claim 9 above, and further in view of Miraki (US 5,318,535).

In regards to claim 10, Campbell teaches that the distal end of the catheter [14] comprises a port to permit inflation fluid to flow between the lumen of the catheter and the interior volume of the balloon [20] (column 3, lines 40-43); however, Campbell is silent about whether the distal end of the catheter terminates within the interior volume of the balloon (Figure 1). Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) wherein the distal end of a catheter (shaft [32]) terminates within the interior volume of a balloon (balloon [132]) (Figures 6-7). It

would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal end, of the catheter of Campbell, to terminate within the interior volume of the balloon, as taught by Miraki, as an obvious design choice to the user, as a distal end of a catheter can be placed within a balloon with the proximal end of the balloon about the distal end of the catheter (Figures 6-7) or the distal end of the catheter can be placed about the proximal end of a balloon.

In regards to claim 11, Campbell teaches that the distal end of the catheter [14] is fixedly connected to the stiffening member [46] (Figures 5-5A) (column 4, lines 1-7); however, Campbell is silent about whether the distal end of the catheter terminates within the interior volume of the balloon (Figure 1). Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) wherein the distal end of a catheter (shaft [32]) terminates within the interior volume of a balloon (balloon [132]) (Figures 6-7). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal end, of the catheter of Campbell, to terminate within the interior volume of the balloon, as taught by Miraki, as an obvious design choice to the user, as a distal end of a catheter can be placed within a balloon with the proximal end of the balloon about the distal end of the catheter (Figures 6-7) or the distal end of the catheter can be placed about the proximal end of a balloon.

In regards to claim 12, Campbell is silent about whether the distal end of the catheter [14] terminates within the interior volume of the balloon (Figure 1) and does not teach that the distal end of the catheter is in sliding engagement with the stiffening member, since Campbell teaches that the distal end of the catheter [14] is fixedly connected to the stiffening member [46] (column 4, lines 1-7). Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) wherein the

distal end of a catheter (shaft [32]) terminates within the interior volume of a balloon (balloon [132]) and the distal end of the catheter is in sliding engagement with a stiffening member (guide wire [12]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal end, of the catheter of Campbell, to terminate within the interior volume of the balloon, as taught by Miraki, as an obvious design choice to the user, as a distal end of a catheter can be placed within a balloon with the proximal end of the balloon about the distal end of the catheter (Figures 6-7) or the distal end of the catheter can be placed about the proximal end of a balloon. It also would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the distal end, of the catheter of Campbell, to be in sliding engagement with the stiffening member, as taught by Miraki, as the sliding engagement between the distal end of the catheter and the stiffening member will allow the stiffening member to be freely movable axially for efficiently guiding the catheter to a target site in a patient's body (column 8, lines 60-63).

12. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, as applied to claim 15 above, and further in view of Walker et al (US 5,454,788).

In regards to claims 16 and 17, Campbell does not teach that the distal end of the stiffening member [18] comprises a retaining portion. Walker et al teaches a balloon catheter (Figure 31), wherein the distal end of a stiffening member (guide wire [22]) comprises a retaining portion (collar member [46] in the shape of a pierced sphere or ball member), the retaining portion having an exterior cross-sectional area that is greater than an interior cross-sectional area of a cannula (stop rib [239] of sleeve portion [42]) so as to prevent the distal end

of the stiffening member from passing through the cannula, the retaining member being disposed between a distal end of the cannula and the distal terminus of a passageway (orifice [40]) of a sleeve [42]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the catheter of Campbell, with a retaining portion that is disposed between a distal end of the cannula and the distal terminus of the passageway of the sleeve, as taught by Walker et al, as the retaining member will act as a stop means to limit the distal movement of the sleeve along the stiffening member by the engagement of the cannula with the retaining member (column 26, lines 32-37).

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, as applied to claim 19 above, and further in view of Weldon et al (US 5,419,765).

In regards to claim 20, Campbell teaches that the inflation device comprises a syringe [32] (Figures 1-4); however, Campbell is silent about whether the connector [16] comprises a female luer fitting and the syringe comprises a male luer fitting, the male luer fitting engaged with the female luer fitting. Weldon et al teaches a balloon catheter (Figures 8-10), wherein a connector of the catheter (tube [56]) comprises a female luer fitting (female luer connector fitting [74]) and a syringe comprises a male luer fitting (male luer fitting [72]), the male luer fitting engaged with the female luer fitting (Figures 9-10). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the connector and syringe, of the catheter of Campbell, with female and male luer fittings, respectively, as taught by Weldon et al, as the luer-lock engagement of the male luer fitting of the syringe and the

female luer fitting of the connector of the catheter will prevent the inadvertent separation of the syringe from the catheter (column 7, lines 61-68 to column 8, lines 1-6).

14. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, as applied to claim 1 above.

In regards to claim 22, in the current embodiment (Figures 1-6), Campbell does not teach that the stiffening member [18][46] comprises a lumen configured to accommodate the passage of a wire guide. However, Campbell teaches a further embodiment (Figures 7-8) wherein a stiffening member (tube member [86] with spanning region [88]) comprises a lumen configured to accommodate the passage of a wire guide (guidewire [82]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the catheter of the current embodiment of Campbell (Figures 1-6), with a lumen to accommodate the passage of a wire guide, as taught by the further embodiment of Campbell (Figures 7-8), as it is common practice in the art to place or position catheters in a patient's body over a wire guide (column 2, lines 18-19)(column 2, line 36).

15. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell, as applied to claim 1 above, and further in view of Swanson (US 5,605,543).

In regards to claims 23 and 24, Campbell is silent about whether the stiffening member [18] has a first physical property at a first location and a second physical property at a second location, wherein the first physical property is different from the second physical property. Swanson teaches a balloon catheter [10] (Figure 1) with a stiffening member (guidewire tube

[20]) with a variance in the physical property of stiffness between two locations: the stiffening member is composed of a proximal guidewire tube [21] and a distal guidewire tube [22], with the proximal guidewire tube being stiffer than the distal guidewire tube (column 4, lines 43-52). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the catheter of Campbell, with a variance in the physical property of stiffness between two locations, as taught by Swanson, in order to enhance the pushability of the resultant catheter since the proximal end is stiffer than the distal end (column 4, lines 53-55).

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell and Swanson, as applied to claim 23 above, and further in view of Miraki.

In regards to claim 25, in a modified catheter of Campbell and Swanson, Campbell does not teach that the stiffening member [18] has a tapered cross-section. Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) wherein a stiffening member (guide wire [12]) has a tapered cross-section. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member, of the modified catheter of Campbell and Swanson, to have a tapered cross-section, as taught by Miraki, as tapering of the stiffening member will provide an enhanced degree of flexibility toward the distal end of the stiffening member (column 14, lines 44-47).

Response to Arguments

17. Applicant's arguments with respect to claims 1-6, 9-12, and 15-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: C. (US 2001/0056273), Mulder (US 5,700,242), and Tsugita et al (US 6,176,851).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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